72. A pharmaceutical injectable composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier for parenteral administration.

73. A pharmaceutical implantable composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier for percutaneous implantation.

74. A pharmaceutical inhalable composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier for nasal administration.

REMARKS

Claims 1-71 are pending in the present patent application. The Examiner has withdrawn all of the pending claims except for claim 2 based on applicants' election in response to the Examiner's restriction requirement. Claim 2 has been amended to be directed to a pharmaceutical tablet composition. New claims 72, 73 and 74 are directed to pharmaceutical injectable, implantable and inhalable compositions. Support for the new claims can be found throughout the specification, and more specifically at page 22, lines 28-32, page 26, lines 23-31, and page 27, lines 1-34. Claims 2 and 72-74 are presented for reconsideration.

Claim 2 is rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,506,151 of Ito et al. The Examiner states that Ito teaches the EDU compound in the presence of water (see col. 6, example 1). In response claim 2 has been amended.

In Example 1, which is cited by the Examiner, a EDU solution was prepared by dissolving 2M of EDC into water, followed by hydrolysis. Claim 2 has been amended to recite a pharmaceutical tablet formulation. There is no teaching or suggestion in Ito that EDU in water can be used as a pharmaceutical composition in the form of a tablet. Further, new claims 72 to 74 are also patentable in view of Ito as Ito neither teaches nor suggests a

pharmaceutical injectable, inhalable or implantable composition that is suitable for parenteral, percutaneous implantation or nasal administration, respectively.

The EDU/water solution disclosed in Ito simply is not a composition suitable for use as a tablet or in a form that is injectable, implantable or inhalable. It is well known in the art that water alone is not a suitable pharmaceutical carrier for the claimed mode of administration. As discussed in the present application, "[t]he formulations of the invention are administered in pharmaceutically acceptable solutions, which may routinely contain pharmaceutically acceptable concentrations of salt, buffering agents, preservatives, compatible carriers, adjuvants, and optionally other therapeutic ingredients." (page 25, lines 29-32). Such components are absent in the EDU/water solution disclosed in Ito.

The undersigned appreciated the courtesy extended by the Examiner in the teleconference call of today. As suggested by the Examiner, the claims are amended in view of the Final Office Action. Should the claims be in a condition for allowance, we respectfully request that applicants have the opportunity to amend certain dependent claims, currently withdrawn, to depend on the claims that are found to be in a condition for allowance.

Accordingly, it is respectfully requested that the rejection of claim 2 under 35 U.S.C. § 102 as anticipated by Ito be withdrawn. It is also submitted that new claims 72 to 74 are similarly in a condition for allowance, early notice of which is earnestly requested.

Respectfully submitted,
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AMENDMENTS TO THE CLAIMS SHOWING CHANGES

In the Claims:

2. (Twice Amended) A pharmaceutical tablet composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier.